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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,177

11/20/2006

Joseph M. Ahearn

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EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

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12/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/552,177	AHEARN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GAIL R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/6/06; 4/6/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-14, filed December 1, 2008 is acknowledged and has been entered. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 15-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Accordingly, claims 1-25 are pending. Claims 1-14 are under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "complement C4d associated with platelets" in all occurrences because it is unclear what is encompassed in the recitation of "associated with." Specifically, the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Does it mean related, bound, or within close proximity of?

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The term "greater quantities" in claim 1 is a relative term which renders the claim indefinite. The term "greater" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 2 is vague and indefinite in reciting, "C42b associated with platelets" because it is unclear what is encompassed in the recitation of "associated with." Specifically, the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Does it mean related, bound, or within close proximity of?

Claim 9 is vague and indefinite in reciting, "complement C4d associated with platelets" in all occurrences because it is unclear what is encompassed in the recitation of "associated with." Specifically, the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Does it mean related, bound, or within close proximity of?

The term "greater quantities" in claim 9 is a relative term which renders the claim indefinite. The term "greater" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 10 is vague and indefinite in reciting, "complement C4d associated with platelets" in all occurrences because it is unclear what is encompassed in the recitation of "associated with." Specifically, the term "associated" is a subjective term that lacks a

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comparative basis for defining its metes and bounds. Does it mean related, bound, or within close proximity of?

The term "greater quantities" in claim 10 is a relative term which renders the claim indefinite. The term "greater" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 11 is vague and indefinite in reciting, "complement C4d associated with platelets" because it is unclear what is encompassed in the recitation of "associated with." Specifically, the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Does it mean related, bound, or within close proximity of?

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-5, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-18 and 21 of U. S. Patent No. 7,390,631. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a method of diagnosing or monitoring systemic lupus erythematosus (SLE) using C4d as a marker that is associated with blood cells of a whole blood sample.

U. S. Patent No. 7,390,631 differs from the instant invention in failing to teach that the blood cells are platelets.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to extend the method for diagnosing SLE using the same marker used by U. S. Patent No. 7,390,631, that is associated with other variations of blood cells present in a patient's vasculature such as platelets as taught in the instant invention because platelets constitute obvious variations of cell types present in peripheral blood and it is known that soluble C4d is present in plasma of SLE patients, and has been proven to deposit on cells that express receptors to the C4d such as erythrocytes, and with the knowledge that such receptors are also present in other blood cell populations such as platelets, it would have been obvious to incorporate testing of such cells for the method of diagnosing SLE in the same way as was done with RBCs. One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in using the same labeled anti-C4d antibodies

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used to detect C4d components in RBCs taught in U. S. Patent No. 7,390,631 for application with platelet cells in the instant invention.

4. Claims 1, 3-5, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U. S. Patent No. 7,361,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a method of diagnosing or monitoring systemic lupus erythematosus (SLE) using C4d as a marker that is deposited in blood cells of a whole blood sample.

U. S. Patent No. 7,361,517 differs from the instant invention in failing to teach that the blood cells are platelets.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to extend the method for diagnosing SLE using the same marker used by U. S. Patent No. 7,361,517, that is associated with other variations of blood cells present in a patient's vasculature such as platelets as taught in the instant invention because platelets constitute obvious variations of cell types present in peripheral blood and it is known that soluble C4d is present in plasma of SLE patients, and has been proven to deposit on cells that express receptors to the C4d such as erythrocytes, and with the knowledge that such receptors are also present in other blood cell populations such as platelets, it would have been obvious to incorporate testing of such cells for the method of diagnosing SLE in the same way as was done with RBCs. One of ordinary skill in the art at the time of the instant invention would

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have reasonable expectation of success in using the same labeled anti-C4d antibodies used to detect C4d components in RBCs taught in U. S. Patent No. 7,361,517 for application with platelet cells in the instant invention.

5. Claims 1, 3-5, and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 8, 9, 15, 18-20, 24, and 26 of copending Application No. 10/866,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a method of diagnosing or monitoring inflammatory disease using C4d as a marker that is deposited in blood cells of a whole blood sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application No. 10/866,509 differs from the instant invention in failing to teach that the blood cells are platelets.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to extend the method for diagnosing SLE using the same marker used by Application No. 10/866,509, that is associated with other variations of blood cells present in a patient's vasculature such as platelets as taught in the instant invention because platelets constitute obvious variations of cell types present in peripheral blood and it is known that soluble C4d is present in plasma of SLE patients, and has been proven to deposit on cells that express receptors to the C4d such as erythrocytes, and with the knowledge that such receptors are also present in other



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blood cell populations such as platelets, it would have been obvious to incorporate testing of such cells for the method of diagnosing SLE in the same way as was done with RBCs. One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in using the same labeled anti-C4d antibodies used to detect C4d components in RBCs taught in Application No. 10/866,509 for application with platelet cells in the instant invention.

6. Claims 1, 3-5, and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 10-13, 18, and 19 of copending Application No. 10/545,052. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a method of diagnosing or monitoring inflammatory disease using C4d as a marker that is deposited in blood cells of a whole blood sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application No. 10/545,052 differs from the instant invention in failing to teach that the blood cells are platelets.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to extend the method for diagnosing SLE using the same marker used by Application No. 10/545,052, that is associated with other variations of blood cells present in a patient's vasculature such as platelets as taught in the instant invention because platelets constitute obvious variations of cell types present in

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peripheral blood and it is known that soluble C4d is present in plasma of SLE patients, and has been proven to deposit on cells that express receptors to the C4d such as erythrocytes, and with the knowledge that such receptors are also present in other blood cell populations such as platelets, it would have been obvious to incorporate testing of such cells for the method of diagnosing SLE in the same way as was done with RBCs. One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in using the same labeled anti-C4d antibodies used to detect C4d components in RBCs taught in Application No. 10/545,052 for application with platelet cells in the instant invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3-5, and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahearn et al. (7,390,631).

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Ahearn et al. disclose methods of diagnosing systemic lupus erythematosus (SLE) using C4d as markers that are present in plasma portion and then deposited into erythrocytes of peripheral blood samples from patients having SLE (Abstract). According to Ahearn et al., activation of classical pathway components that accompany inflammatory disease activity can lead to deposition of C4d from plasma into erythrocytes present in the blood sample (Abstract and col. 4, lines 46-61). In practice, Ahearn et al. specifically teach contacting the patient's whole blood sample to labeled polyclonal or monoclonal antibodies that specifically bind to C4d (anti-C4d antibody) present in the blood sample; hence, associated to platelets. The anti-C4d antibody would bind to C4d present in the blood sample that is deposited on erythrocytes (col. 6, lines 54-67). The C4d result in the patient is compared to the level of the C4d on the surface of erythrocytes in a normal control sample, whereupon a significant increase in the level of the C4d in erythrocytes of the patient sample in comparison to normal control (no SLE) provides indication of the presence of SLE in the patient (col. 7, line 60 to col. 8, line 10 and lines 36-52). See also Example 2.

Ahearn et al. also disclose a kit for diagnosing SLE using antibodies specific for complement pathway components. Ahearn et al. specifically teach that the kit includes fluorescent labeled anti-C4d antibodies (col. 7, lines 21-34 and 52-60).

In as far as the recitation of "quantitation of complement C4d associated with platelets", "comparing the quantity of complement C4d associated with platelets" and "greater quantities of C4d associated with platelets," Ahearn et al. specifically provided in column 2, lines 17-19 that all of red blood cells, platelets, and white blood cells can

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be targeted in SLE. It is therefore reasonable within the context of the broadly interpreted claim to interpret "associated" to encompass any and all complement pathway component C4d that is present in the whole blood sample including those that are present in plasma and those that deposited into erythrocytes, because the plasma portion having C4d and the C4d that deposited into erythrocytes are within close association or proximity with platelets present in whole blood sample of SLE patients. It is proper for purposes of this anticipation rejection to interpret "associated with platelets" as within close association or proximity with platelets present in whole blood sample because unpatented claims are given the broadest interpretation consistent with the specification.

8. Claims 1, 3, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Buyon et al. (Assessment of Disease Activity and Impending Flare in Patients with Systemic Lupus Erythematosus, Arthritis and Rheumatism, Vol. 35, No. 9 (September 1992)).

Buyon et al. teach a method of identifying systemic lupus erythematosus (SLE) using C4d as markers that are present in plasma portion of peripheral blood samples from patients having SLE (Abstract). Buyon et al. specifically teach that analysis of SLE disease course reveal that elevated C4d has the most sensitivity with regards to disease flare (p. 1028, col. 2). In practice, Buyon et al. specifically teach contacting the plasma portion of the patient's whole blood sample to labeled monoclonal antibodies that specifically bind to C4d (anti-C4d antibody) present in the blood sample; hence

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associated with platelet cells (p. 1029, col. 2, 2<sup>nd</sup> and 3<sup>rd</sup> full par.). The result is compared to the level of the C4d in a normal control sample, whereupon a significant increase in the level of the C4d in the plasma of the patient sample in comparison to normal control (no or inactive SLE) provides indication of the presence of SLE in the patient.

In as far as the recitation of "quantitation of complement C4d associated with platelets", "comparing the quantity of complement C4d associated with platelets" and "greater quantities of C4d associated with platelets," it is therefore reasonable within the context of the broadly interpreted claim to interpret "associated" to encompass any and all complement pathway component C4d that is present in the whole blood sample including those that are present in plasma, because the plasma portion having C4d are within close association or proximity with platelets present in whole blood sample of SLE patients. It is proper for purposes of this anticipation rejection to interpret "associated with platelets" as within close association or proximity with platelets present in whole blood sample because unpatented claims are given the broadest interpretation consistent with the specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buyon et al. (Arthritis and Rheumatism, Vol. 35, No. 9 (September 1992)) in view of Freysdottir et al. (A flow cytometric assay for measuring complement receptor 1 (CR1) and complement component C4d on erythrocytes, Journal of Immunological Methods 142: 45-52 (1991)).

Buyon et al. is discussed supra. Buyon et al. differ from the instant invention in failing to teach that the anti-C4d antibody is labeled with a fluorescence moiety for quantitation by flow cytometric analysis.

Freysdottir et al. teach a flow cytometric quantitative assay method of determining amount of complement component (fragment) C4d deposited on surfaces of red blood cells or RBCs (erythrocytes) in a sample (Abstract). Freysdottir et al. specifically teach determining amounts of C4d deposited on surface of RBCs, and comparing the results to normal healthy individual assay results (p. 46, col. 1, 1<sup>st</sup> full par. to col. 2, 3<sup>rd</sup> full par.; and p. 49, 2<sup>nd</sup> full par). The sample is contacted with labeled

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anti-C4d MAb to bind C4d that deposited on RBCs. Erythrocyte concentration C4d is measured flow cytometrically (p. 46, col. 1, 1<sup>st</sup> full par. bridging to p. 47 col. 1, 1<sup>st</sup> par. and Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the enzyme label of Buyon with fluorescent label as taught by Freysdottir in order to immunologically assay for the amount of C4d using flow cytometry because Freysdottir taught application of fluorescent labeled antibodies for binding and flow cytometric detection of complement pathway components. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate flow cytometric analysis of C4d as taught by Freysdottir into the diagnostic method of assessing SLE using C4d as taught by Buyon because Freysdottir showed that flow cytometric analysis of complement pathway components such as C4d and CR1 provides increased accuracy and discrimination between different related components.

10. Claims 2, 6-8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahearn et al. (7,390,631) or Buyon et al. (Arthritis and Rheumatism, Vol. 35, No. 9 (September 1992)) in view of Freysdottir et al. (Journal of Immunological Methods 142: 45-52 (1991)) as applied to claims 1, 3-5, and 9-12 above, in further view of Kuhne et al. (Flow Cytometric Evaluation of Platelet Activation in Blood Collected Into EDTA vs. Diatube-H, American Journal of Hematology 50: 40-45 (1995)).

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Ahearn et al. or Buyon et al. and Freysdottir et al. are discussed supra. Note that Ahearn et al. also disclose a kit for diagnosing SLE using antibodies specific for complement pathway components. Ahearn et al. specifically teach that the kit includes fluorescent labeled anti-C4d antibodies (col. 7, lines 21-34 and 52-60).

Ahearn et al. or Buyon et al. and Freysdottir et al. differ from the instant invention in failing to teach quantitating CD42b associated with platelet obtained from an individual.

Kuhne et al. teach flow cytometrically measuring the amount of platelet cell surface antigen in whole blood samples (Abstract). In practice, Kuhne et al. collected whole blood samples into Diatube-H vacutainer tubes and then contacted the sample with fluorochrome-labeled monoclonal antibodies which are specific for binding with platelet cell surface antigens such as CD42b (GpIb). Binding of fluorescent labeled anti-CD42b antibody with CD42b expressed on platelets was detected and measured using flow cytometry (p. 41, cols. 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to further flow cytometrically detect CD42b that is present in platelets of whole blood samples as taught by Kuhne into the method of diagnostic methods of identifying SLE as taught by Ahearn or Buyon as modified by Freysdottir because both of Freysdottir and Kuhne specifically taught application of flow cytometric analysis to detect both soluble antigen or cell surface antigen present in whole blood, both references of which suggest advantage of flow cytometric analysis in achieving increased level of accuracy and discrimination of different related antigenic



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components, as such differential multivariant analysis is indeed, the power of flow cytometry.

11. No claims are allowed.

***Remarks***

12. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Sirois et al. (An Enzyme-Linked Immunosorbent Assay for the Detection of Complement Components on Red Blood Cells, Am. Journ. Clin. Path. 82 (1): 67-73 (July 1984)) teaches detection of complement pathway component C3d deposited on red blood cells which provides diagnosis of inflammatory disease including SLE (Table 4).

Senaldi, G., et al. (Correlation of the activation of the fourth component of complement (C4) with disease activity in systemic lupus erythematosus, Ann. Rheum. Dis., 1988, Vol. 47: 913-917) teaches that there is a strong correlation between C4d and C3d in plasma of SLE patients (Abstract and p. 914, cols. 1 and 2).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIL R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

December 4, 2008